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Award Number: DAMD17-96-2-6019

TITLE: Cardiovascular Responsivity, Phsyical and Psychosocial Job  
Stress, and the Risk of Preterm Delivery

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REPORT DATE: November 2000

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;  
Distribution unlimited

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20010419 058

# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE November 2000		3. REPORT TYPE AND DATES COVERED Final (1 Oct 96 - 1 Nov 00)	
4. TITLE AND SUBTITLE Cardiovascular Responsivity, Physical and Psychosocial Job Stress, and the Risk of Preterm Delivery				5. FUNDING NUMBERS DAMD17-96-2-6019	
6. AUTHOR(S) Maureen C. Hatch, Ph.D.					
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9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES					
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; Distribution unlimited					12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words)  Preterm delivery (that is, delivery prior to 37 completed weeks of gestation) has proved to be a remarkably intractable problem in the U.S. and one that appears to be quite prevalent among defense women. While defense women as a group are young, healthy, fit and have excellent access to prenatal care, their preterm delivery rates are higher than average. However, their work may involve more physical activity than is usual and women may work right up to the time of delivery. This study, a military/civilian collaboration, will assess the effect of various sources of job stress as risk factors for preterm delivery among military women seeking prenatal care at Wilford Hall Medical Center. The role of cardiovascular reactivity in the stress response and how this affects risk of preterm delivery will also be examined. Recruitment, now complete, took longer than anticipated due to a high rate of ineligibles. We propose to complete the analyses under a no-cost extension.					
14. SUBJECT TERMS  Preterm delivery, stress, cardioresponsivity, Women's Health					15. NUMBER OF PAGES 6
					16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified		20. LIMITATION OF ABSTRACT  Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)  
Prescribed by ANSI Std. Z39-18  
298-102

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## **DOD Final Report**

### **(4) INTRODUCTION:**

Preterm birth is a major cause of perinatal morbidity and mortality. Nationally about 8%-10% of all deliveries are preterm but the rates in subgroups of the population range from 4% -- which is the rate in many other developed countries -- to as high as 18%. Established risk factors, such as black race and low socioeconomic status, explain less than a third of spontaneous preterm births, so there is a considerable interest in identifying significant new determinants of premature delivery. Currently, the potential roles of psychosocial stress and physical strain have attracted attention. These factors may be especially relevant for women who have a marked hemodynamic response to stress.

The overall goal of this study is to examine the effects of physical and psychosocial stress as risk factors for preterm birth among an ethnically diverse population of active duty military women recruited from the prenatal clinic at Wilford Hall Medical Center during their first trimester and followed to delivery. A secondary goal is to evaluate the role of the maternal circulatory response to stress in raising the risk for preterm delivery.

### **(5) BODY:**

As we described in previous annual reports, we have encountered a substantial number of ineligibles in our target population, due largely to women who were transferring to another base or leaving the service entirely prior to their expected due date. We had not anticipated this in planning the study and projecting the rate of accrual. As a consequence, when we reached Year 4, at which point recruitment was scheduled to be completed, we had a total of only 641 participants, considerably short of the enrollment target of 1000 women.

We faced a dilemma. We could adhere to the study timeline, necessarily accepting a smaller sample and hence less statistical power, or we could extend recruitment into Year 4 in order to achieve a sample size closer to our initial goal. This last is the option we preferred, especially given the importance of analyzing data for subgroups of the population (e.g., race, age). We are therefore requesting a no-cost extension of the study to cover an additional 9 months, until June 30, 2001. Assuming the DOD agrees, we would submit a supplemental final report at that time. There will of course be no further contact with study subjects although delivery records for the last participants to be enrolled may be reviewed during this period.

Following is a record of our progress to date. In last year's report we described the headway on Tasks 8-11 (Tasks 1-7 having been completed). Below is an update on Tasks 8-11 as well as a status report on Tasks 12-15.

### **Task 8 - Enroll subjects**

A total of 841 subjects have been enrolled, 200 more than at the end of last year. Of these 683 have completed the baseline questionnaire, 598 have completed both baseline and follow-up questionnaires, and 429 have completed the cardio monitoring. As reported last year, participation in the cardiovascular testing is averaging at best 70%. Subjects claim they are too busy but offers of flexible scheduling did not meet with success.

### **Task 9 - Enter questionnaires into database**

Thus far questionnaire data have been entered for approximately 700 participants. Logic and range checks by the investigators have uncovered no errors.

### **Task 10 - Integrate psychophysiological data**

All of the cardiomonitoring data have been integrated into the main data files.

### **Task 11 - Abstract medical records**

Records have been abstracted for 590 of the 841 women enrolled.

### **Task 12 - Travel**

The PI plans to make a "close-out" visit to San Antonio at the end of November.

### **Task 13 - Clean data files**

A major focus of our recent work has been on reviewing the data files to insure that all of the data collected have been entered into the computer or, in the case of the cardiac monitoring data, integrated into the main file. The task is virtually completed, with the exception of materials from the final participants.

### **Task 14 - Statistical Analyses**

Although we did begin conducting preliminary analyses on a subset of the entire cohort, we became concerned that the impressions we formed might bias our approach to analysis of the complete cohort. We decided to wait until the full data set was ready before proceeding any further. Therefore, at this time, we are presenting no analytic results. Now that the last subjects are enrolled, we should be able to finalize the data set and begin the actual analyses very shortly.

**Task 15** - Preparation of manuscripts and final report awaits results of the full analyses.

**(6) KEY RESEARCH ACCOMPLISHMENTS:**

- Have assembled a large and diverse cohort of pregnant military women who should contribute very useful data on many aspects of the research question.
- The high response rate among eligible women helps to insure validity of the data collected.
- The data set on cardioresponsivity among pregnant women is virtually unique, both in nature and size.

**REPORTABLE OUTCOMES:**

None as yet.

**(7) CONCLUSIONS:**

None as yet.

**(8) REFERENCES:**

N/A

**(9) APPENDICES:**

N/A

**(10) BINDING:**

N/A

**(11) FINAL REPORTS:**

Since we have not conducted analyses, there are no publications or meeting abstracts based on this study.

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